546 HFI-35 9/4/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (201) 331-2904

August 19, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED
Mel Weiss, President
Consumer Product Testing Company
70 New Dutch Lane
Fairfield, New Jersey, 07004

RELEASE
REVIEWED BY C.O. DATE 8/29/97

FILE NO.: 97-NWJ-47

Dear Mr. Weiss:

An inspection was conducted of your testing laboratory located at 70 New Dutch Lane, Fairfield, New Jersey, by the U.S. Food and Drug Administration on June 6 through July 10, 1997. The inspection revealed significant deviations from the current good manufacturing practices (21 CFR 210/211) concerning the performance of analyses and lack of following written procedures relating to analytical methodology. The violations were presented to your attention on a FD-483 List of Observations, at the close of the inspection. These CGMP deviations cause articles of drug assayed for release for further manufacture and/or release for commercial distribution to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act, in that the methods used in and the controls used for the manufacturing, processing, and holding of drug products are not in conformance with current GMP regulations part 210 and 211.

The significant CGMP deviations noted are as follows:

Analytical Laboratory

1. The firm did not comply with their SOP #[redacted] "Action on Apparent Non-Conformance of Test Results", in that no investigation was conducted and a Non-Conformance Investigation Form was not prepared after duplicate initial assay values for Isoptin 2.5 mg/ml (Verapamil HCl) Ampules, Study [redacted] were 87.5% and 93.8% of label claim (specification is [redacted].

The sample was reinjected and the passing retest result (96.8%) was reported to their client.

2. Duplicate assays values were averaged and the results were reported to clients, while the individual results did not meet specifications. For example:

   a. Duplicate assay values for Prednisone 5 mg tablets, Study [redacted] were 5.532 mg and 5.374 mg (110.64% and 107.48% label claim). Only the average of the two values (5.45 mg = 109.0%) was reported to their client. The specification is [redacted] mg comparable to 90 - 110% label claim.

3. Failure to comply with SOP #[redacted] in that no investigation was performed regarding an out of specification LOD value of 10.14% (specification is NMT [redacted] produced during testing of Pectin USP, Study [redacted] The sample was retested resulting in a 9.92% LOD value. The out of specification value and the in-specification value were averaged together resulting in a 10.0% value. This averaged LOD value was then used to calculate the assay value.

Microbiology Laboratory

4. Failure to perform the Microbial Preparatory Testing, as required by USP, on products tested, including: 3 in 1 Antibiotic Ointment, Hydrocortisone Acetate Cream, Antiseptic Jel, Cool Jel, Water Jel, First Aid Cream with Moisturizing Aloe, Bacitracin Raw Material, Neomycin Sulfate, and Germaben II.

5. The firm did not have data to support the three month expiration date assigned to prepared dehydrated media used for sterility testing and microbial limits testing.

6. The validation of the autoclave cycle used for sterilizing media was inadequate. Examples:

   a. Growth promotion was only performed on one load of autoclaved media to assure growth promotion capabilities. Also, there is no indication that media located in the hot spots of the autoclave were evaluated for growth promotion capabilities.

   b. The failure of the drain temperature to maintain a temperature of 121 ^{0}C for the duration of the cycle was not evaluated.

7. No assurance that products undergoing anti-microbial preservative effectiveness testing (e.g. Antiseptic Jel, Aspercreme Lotion with Aloe, Arthritis Hot Cream, Germaben II) are maintained at the USP temperature requirement of 20^0 - 25^0C. For the 28-day incubation period, products are stored on laboratory benches in a laboratory lacking temperature controls.

We have reviewed your response letter dated July 22, 1997 and consider your response to many of the observations listed on the FD-483 to be unsatisfactory. Our comments and concerns will be addressed in a formal response to your firm as soon as possible.

It is your responsibility to ensure that all requirements of the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder are being met. We recommend that you conduct a complete evaluation of your facility for CGMP compliance.

The above list of violations are not to be considered as an all-inclusive list of deficiencies at your facility. Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so that they may take this information into account when considering the award of contracts.

Any additional information you may wish to submit regarding this matter or any questions you may have should be directed to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., Third Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,

Douglas Ellsworth

DOUGLAS ELLSWORTH
District Director
New Jersey District Office

AC:slw